

REMARKS

Claims 1-6 and 8-14 are pending. Claims 8-13 have been withdrawn. New Claim 14 has been added. Claim 1 has been amended to further define Applicants invention and to facilitate prosecution of the above-referenced application. Claim 1 is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 (“Sunshine”), U.S. Patent No. 4,943,565 (“Tencza et al.”), Remington’s Pharmaceutical Sciences p. 1837 (“Remington”), and U.S. Patent No. 6,602,520 (“Schroeder et al.”). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Among the noteworthy features of the claimed solid pharmaceutical dosage form recited in Claim 1, is (i) the inclusion of caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having an average particle size of about 70 to 600 microns, and (ii) wherein at least 86 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

A review of Sunshine et al. does not show it to disclose a composition that includes uncoated ungranulated caffeine. Nor does Sunshine et al. disclose that at least 86 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Accordingly, Claim 1 is patentable over Sunshine et al.

Tencza et al. also is not found to disclose a composition that includes uncoated ungranulated caffeine. Nor does Tencza et al. disclose that at least 86 % of the caffeine dissolves

within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1.

Remington is cited for disclosing that disintegrants may be a substance or a mixture of substances added to a tablet.

Schroeder et al. is cited for teaching rapidly dissolving preparations containing at least one active pharmaceutical ingredient and at least one excipient.

It is respectfully submitted that Tencza et al., Remington, and/or Schroeder et al. do not remedy the deficiencies of Sunshine et al. That is, like Sunshine et al. - Tencza et al., Remington, and Schroeder et al. do not teach or suggest (i) the inclusion of caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having an average particle size of about 70 to 600 microns, and (ii) wherein at least 86 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, in a solid pharmaceutical dosage form.

Accordingly, Applicants respectfully submit that the proposed combination of Sunshine, Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. would not result in a solid pharmaceutical dosage form that includes uncoated ungranulated caffeine, wherein at least 86 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. As such, Claim 1 is patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., whether considered separately or in combination.

Claims 2-6 and 14 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 and 14 are patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., taken separately or in combination.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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